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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/695, 053 10/25/00 DONG

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 EXAMINER

HENLEY III, R

ART UNIT	PAPER NUMBER
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1614

DATE MAILED:

05/04/01

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/695,053	Applicant(s) Qingbin Dong, et al.
Examiner Ray Henley	Art Unit 1614



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

4) Claim(s) 1-22 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-22 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

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CLAIMS 1-22 ARE PRESENTED FOR EXAMINATION

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al. (U.S. Patent No. 5,846,975).

Pan et al. teach the presently claimed compounds (column 3, line 36 - column 6, line 40) and that TTX, a prototypical example of such compounds, was known to be a potent analgesic for late cancer patients with no drug addiction occurring (column 2, lines 8-11) and that it was reportedly effective on relieving pain for lepers (column 2 lines 29-30).

The differences between the above and applicants' claimed subject matter lies in that the patentees do not highlight:

- (1) the presently claimed dosage amounts, regimens and routes of administration;
- (2) pain arising from other conditions than cancer and leprosy;
- (3) the presently claimed lack of adverse effects; and
- (4) the packaging as in present claim 22.

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However, to the skilled artisan, the presently claimed subject matter would have been obvious because:

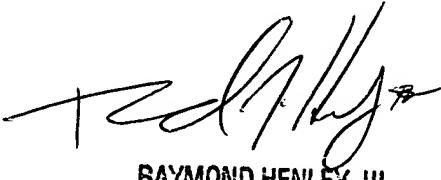
- (1) the determination of the optimum dosage, dosage regimen and route of administration was routine and would have been matters well within the purview of the skilled artisan;
- (2) Given that it was known that late cancer patients could be effectively treated, and the pain suffered by such patients of often severe, the skilled artisan would have readily appreciated that the pain associated with other conditions of the same or less severe nature could also be effectively treated;
- (3) the patentees do not teach that the administration of the compounds produce the presently claimed adverse effects, (such as in present claim 12), and thus skilled artisan would have had no expectation that such effects would occur; and
- (4) it is routine to package pharmaceutical compositions with written material and thus the packaging arrangement of claim 22 would have been obvious. The subject matter of such written material is not matter that falls within the statutes of patent law, but rather would be more properly evaluated under copyright law. In any event, such subject matter would amount to no more than a statement of intended use and would not impart any physical feature to the claimed composition that would not be present or have been obvious from the prior art.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none are allowed.

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The reference cited on the attached form PTO-892 and not relied upon is included to show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.



RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1Q00

Henley; rjh
April 13, 2001